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Pfizer Pharmaceuticals

April 23, 1999

Robert B. Clark
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Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20852

PEDIATRIC PRIORITY LIST

CITIZEN PETITION

The undersigned submits this petition pursuant to 21 C.F.R. §10.30, pursuant to Food and Drug Administration ("FDA") Docket No. 98N-0056, "List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population" (May 20, 1998), and pursuant to paragraph V(c) of FDA, "Guidance for Industry: Qualifying for Pediatric Exclusivity under Section 505A of the Federal Food, Drug and Cosmetic Act" (June 1998), under Section 505A of the Food, Drug and Cosmetic Act, 21 USC §355a, to request the Commissioner of Food and Drugs to add alatrofloxacin to the Priority List of Approved Drugs for Which Additional Pediatric Information May Produce Health Benefits in the Pediatric Population, as published by FDA under Docket No. 98N-0056 ("Priority List").

A. Action Requested

The undersigned requests that the Commissioner add alatrofloxacin to the Priority List.

B. Statement of Grounds

Trovan® is a synthetic broad-spectrum antibacterial agent developed and marketed by Pfizer. It is approved in tablet formulation as trovafloxacin mesylate (NDA # 20-759), and in IV formulation as alatrofloxacin mesylate (NDA # 20-760). Alatrofloxacin mesylate is a prodrug of trovafloxacin mesylate.

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Trovan was approved on December 18, 1997, with indications for the treatment of a variety of infections caused by the strains of the microorganisms set forth in the product's prescribing information. Because many of these infections occur in pediatric patients, additional information on both trovafloxacin mesylate and alatrofloxacin mesylate may produce health benefits in the pediatric population.

FDA included trovafloxacin mesylate in the Priority List but omitted alatrofloxacin mesylate. This omission should be corrected, so that a Written Request for pediatric studies under §111(c) of the Food and Drug Administration Modernization Act of 1997, 21 USC § 355a (c), may include alatrofloxacin mesylate, as well as trovafloxacin mesylate.

C. Environmental Impact

The subject matter of this petition is not within any of the categories of action for which an environmental assessment is required pursuant to 21 C.F.R. §25.22, and is exempt pursuant to 21 C.F.R. §25.30(a), in that it is concerned with routine FDA administrative and management activities.

D. Economic Impact

Not requested.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

PFIZER INC

By Robert B Clark

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cc: Dr. Mark Goldberger, Director (HFD-590)
Ms. Rene Kimsey, Project Manager (HFD-590)

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